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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,884	06/05/2007	Edith Mathiowitz	BU 1594	3510

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EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
07/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,884	MATHIOWITZ ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44,46-51,55-61 and 65-67* is/are pending in the application.

4a) Of the above claim(s) *44,46-51,58-61,65 and 66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-57 and 67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/29/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II (claims 55, 56 and 62-64) in the reply filed on 5/17/2010 is acknowledged. The traversal is on the ground(s) that the cited reference (i.e. Ludwig et al.) does not disclose incorporating growth factors, angiogenic/vasculogenic factors or bone marrow factors in an implant.

Ludwig et al. is generally directed to the method and the device for recruiting target cells (such as progenitor cells) to blood contacting surface (par. 31), and the blood contacting surface can be a prosthesis implanted in vivo (par. 41; thus an implant), and the blood contacting surface (i.e. implant) can be coated with polymer matrix loaded with proteins such as growth factor or cytokines (par. 109 and 130). Furthermore, Ludwig et al. teach that those materials used for modifying target cells can be injected or released from the surface (surface released) (par. 77). Thus, Ludwig et al. teach an implant comprising growth factors and/or cytokines, and this is considered as a drug delivery system.

However, upon the amendment to claim 44, now the technical feature shared between Groups I and II is "implant comprising an external porous housing having pores of a size sufficient to allow movement into the implant of the progenitor cells to be recruited and a drug delivery system comprising growth factors, angiogenic/vasculogenic factors or bone marrow recruiting factors within the housing".

Ludwig et al. do not teach the external housing. However, Dionne et al. teach the use of nylon mesh as a pouch to enclose implant. It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the nylon mesh pouch of

Dionne et al. for the implant of Ludwig et al. Furthermore, a person of ordinary skill in the art would recognize that the pore size of the nylon mesh taught by Dionne et al. should be large enough to allow progenitor cells pass through contact with ligands conjugated on the surface for the implant of Ludwig et al.

Thus, the technical feature shared by Group I and II is known in the art based on Ludwig et al. in view of Dionne et al.

Applicant's election without traverse of species (1) bone marrow factors; (2) nylon; (3) hematopoietic progenitor cells; and (4) GM-CSF in the reply filed on 5/17/2010 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 44, 46-51, 58-61, 65 and 66 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 55-57 and 67 have been considered on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 55-57 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ludwig et al. (US 2003/0082148; of record) in view of Dionne et al. (US PAT. 5,916,554).

Ludwig et al. teach implantable graft prosthesis for recruiting progenitor cells comprising a blood contacting surface having a polymer matrix of micro- or nanoparticles (par. 64), beads (par. 162), film (par. 154), coating (par. 53) or hydrogels (par. 109) (a drug delivery system), conjugated with growth factors or cytokines (par. 22, 109 and 130). Thus, the prosthesis or scaffold of Ludwig et al. is interpreted as an implant as well as a drug delivery system.

Ludwig et al. do not teach an external porous housing having pores of a size sufficient to allow movement into the implant of the progenitor cells to be recruited, and the housing is made of nylon.

Dionne et al. teach a nylon (polyamides) mesh pouch for an implant for easy retrieval of the implant (see entire document).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to try the nylon mesh pouch for implanting the graft prosthesis of Ludwig et al.

Although Ludwig et al. in view of Dionne et al. do not teach the pore size of the nylon mesh being sufficient to allow movement of the progenitor cells into the implant, it would have been obvious to a person of ordinary skill in the art to modify the pore size of the nylon mesh

taught by Dionne et al. to allow the cells (progenitor cells) pass through the mesh and then contact the ligand (e.g. growth factors) attached to the surface of the polymer matrix (scaffold/graft/prosthesis) since the purpose of the implant taught by Ludwig et al. is to recruit cells in the blood stream.

Although Ludwig et al. in view of Dionne et al. do not particularly teach a drug delivery system for bone marrow recruiting factors, Ludwig et al. teach that target cells modification can be carried out by injection or surface release of cytokines or growth factors (par. 77), GM-CSF and/or VEGF is administered to a subject to mobilize target cells including progenitor cells in blood (par. 80), and growth factors or cytokines can be conjugated to the contacting surface as a ligand (par. 130). Therefore, it would have been obvious to a person of ordinary skill in the art to have GM-CSF coated or conjugated as a ligand on the blood contacting surface of the scaffold or implant of Ludwig et al.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651